CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-529

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-529

Organon USA, Inc.
Attention: Edward Nellis
Regulatory Scientist
375 Mount Pleasant Avenue
West Orange, NJ 07052

Dear Mr. Nellis:

Please refer to your new drug application (NDA) dated September 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IMPLANON™ (etonogestrel implant) 68 mg For Subdermal Use Only.

We acknowledge receipt of your submissions dated June 17, July 26, August 5, 23, 31, October 27, 2005, January 16, March 14, April 13, 14, May 3, 15, 23(2), 25, June 26, 29 (2), and 30 (2), July 7 (2), 10 (2), 11 (2), July 12, and July 17 2006.

Your submission of January 16, 2006 constituted a complete response submission to the June 14, 2005 Approvable letter.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling and submitted labeling (package insert submitted **July 17, 2006,** patient package insert submitted **July 17, 2006**, and immediate container and carton labels submitted **June 29, 2006)**. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-529**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated July 12, 2006. This commitment is listed below.

1. **Description of Commitment:** To conduct and submit interim and final study reports for a postmarketing study of insertion and removal complications involving at least 10,000 subjects

Protocol Submission:	within 45 days of the date of this letter
Study Start:	within 2 months of Division concurrence with your protocol or within 2 months of product launch, whichever is later
Interim Report Submission:	quarterly
Final Report Submission:	within 5 years of the date of this letter

Submit the clinical protocol to your IND for this product. Submit all interim and final study reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report and the number of patients entered into this study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure